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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,794	08/03/2001	Christoph Wagener	4121-124	9609

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,794	WAGENER ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 5/19/04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/831,794 is acceptable and a RCE has been established. Claims 1-2, 5-10 are pending and claims 1-2, 6, 8 are currently under prosecution. An action on the RCE follows.
2. Claims 5, 7, 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made in Paper No. 7.
3. Claims 1, 2, 6, and 8 are under examination.
4. It is acknowledged that the method claims 9-10 will be rejoined upon allowance of the composition claims under MPEP 821.04.
5. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

6. The rejection of claims 1-2, 6, 8 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and

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readily available to the public; (2) reproducible from the written description is withdrawn in view of the declaration filed 11/21/03 and completion of the deposit requirements.

Response to Arguments

7. The rejection of claims 1, 2, 6, and 8 under 35 U.S.C. 102(b) as being anticipated by Drzeniek et al (Cancer Letters 56:173-79, 1991) as evidenced from the specification is maintained.

The response filed 5/19/04 has been carefully considered but is deemed not to be persuasive. The response states that claim 9 recites a method and the references of Drzeniek et al and Prall is not anticipatory unless it discloses each and every limitation of the claim and Applicant's submit that one skill in the art would not realize that the presently claimed composition comprising the claimed antibody would inhibit angiogenesis by blocking CD66a receptors on tumor endothelial cells and in response to the Offices contention that the antibodies would inherently reduce angiogenesis and the systems set forth in the cited references do not mention or discuss tumor endothelial cells and the use of the present antibody and both references could not possibly cause the reduction of tumors (see pages 5-6 of response).

In response to this argument, claim 9 is a method claim and not examined. In addition, as stated in the rejection the intended use is given no patentable weight and as such, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There is no structural difference between the claimed antibody and the prior art antibody because as admitted in the specification they are the same (see rejection).

8. The rejection of claims 1, 2, 6, 8 under 35 U.S.C. 102(b) as being anticipated by Prall et al (The Journal of Histochemistry and Cytochemistry 44:35-41, 1996) is maintained.

The response filed 5/19/04 has been carefully considered but is deemed not to be persuasive. The response states that claim 9 recites a method and the references of Drzeniek et al and Prall is not anticipatory unless it discloses each and every limitation of the claim and Applicant's submit that one skill in the art would not realize that the presently claimed composition comprising the claimed antibody would inhibit angiogenesis by blocking CD66a receptors on tumor endothelial cells and in response to the Office's contention that the antibodies would inherently reduce angiogenesis and the systems set forth in the cited references do not mention or discuss tumor endothelial cells and the use of the present antibody and both references could not possibly cause the reduction of tumors (see pages 5-6 of response).

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In response to this argument, as stated in the rejection the intended use is given no patentable weight and as such, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There is no structural difference between the claimed antibody and the prior art antibody because as admitted in the specification they are the same (see rejection).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ^{JERRY SIEW} ~~Christina Chan~~, can be reached at (571) 272-⁰⁷⁸⁷ ~~0841~~.

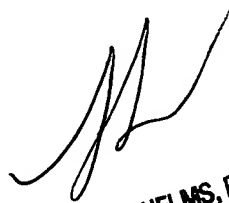
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11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectively,

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER